IN THE UNITED STATES COURT OF FEDERAL CLAIMS
OFFICE OF SPECIAL MASTERS

No. 08-0307V
Filed: August 26, 2013

Sahra Hashi, by SAFIA WEGED and HUSSEIN H. HASHI, her parents,	*	
Petitioners,	*	Autism; Statute of Limitations; First Symptom or Manifestation of Onset; Significant Aggravation
v.	*	
SECRETARY OF HEALTH AND HUMAN SERVICES,	*	
Respondent.	*	

Elaine W. Sharp, Esq., Whitfield, Sharp & Sharp, Marblehead, MA, for petitioners.
Heather L. Pearlman, Esq., U.S. Dept. of Justice, Washington, DC, for respondent.

ORDER AND RULING DISMISSING CAUSATION IN FACT CLAIM[1]

Vowell, Special Master:

On April 11, 2012, respondent filed a motion to dismiss this claim, asserting that the petition was untimely filed. Petitioners filed their response to respondent's motion on July 16, 2012. Although petitioners' amended petition, filed June 29, 2011, asserts both an actual causation and significant aggravation claim,[2] petitioners appear to rely only on a signification aggravation claim in their response to respondent's motion to dismiss.

For the reasons set forth below, petitioners' causation in fact claim is DISMISSED. If petitioners intend to continue pursuing a significant aggravation claim, they shall file a second amended petition setting forth the facts upon which such claim is

[1] Because this ruling and order contains a reasoned explanation for the action in this case, I intend to post it on the United States Court of Federal Claims' website, in accordance with the E-Government Act of 2002, Pub. L. No. 107-347, § 205, 116 Stat. 2899, 2913 (codified as amended at 44 U.S.C. § 3501 note (2006)). In accordance with Vaccine Rule 18(b), petitioners have 14 days to identify and move to delete medical or other information, the disclosure of which would constitute an unwarranted invasion of privacy. If, upon review, I agree that the identified material fits within this definition, I will delete such material from public access.

[2] Petitioners allege that Sahra's vaccines "caused or exacerbated progressive encephalopathy with autistic features, the severe sequelae of which continue to date." Amended Petition at ¶ 11.

based by September 25, 2013. Petitioners are also hereby ordered to file an expert report to support their significant aggravation claim by November 25, 2013. Such a report must clearly indicate the expected progression of Sahra's disorder and how that progression was altered by vaccines received less than 36 months from the date of filing of the original petition in this case. If the expert relies upon facts other than those set forth in Section II below, the expert must identify the source of the information upon which he or she relies, and explain why he or she does so.

I. Procedural History.

On April 22, 2008, petitioners filed a short-form petition authorized by Autism General Order #1[3] for compensation under the National Vaccine Injury Compensation Program, 42 U.S.C. § 300aa-10, *et seq*.[4] [the "Vaccine Act" or "Program"], on behalf of their minor daughter, Sahra Hashi ["Sahra"]. By filing a short form petition, petitioners joined the Omnibus Autism Program ["OAP"],[5] alleging that Sahra had a disorder on the autism spectrum and that one or more vaccines listed on the Vaccine Injury Table[6] were causal of her condition. Petitioners did not file any medical records or details regarding Sahra's injuries with their short-form petition.

The special master previously assigned to this case ordered petitioners to complete their petition by filing the statutorily required medical records[7] and a "Statement Regarding Onset" addressing the timeliness of the petition. Order, issued Apr. 28, 2008. On May 20, 2008, respondent filed her Rule 4(c) report ["Res. Rpt."], stating that she could not assess the merits of petitioners' claim without the outstanding medical records. Res. Rpt. at 1.

Petitioners filed their first set of medical records on October 25, 2010.[8] No

[3] Autism General Order #1, 2002 WL 31696785 (Fed. Cl. Spec. Mstr. July 3, 2002), is available at: http://www.uscfc.uscourts.gov/sites/default/files/autism/Autism+General+Order1.pdf. The theories of causation specifically addressed in Autism Gen. Order #1 were that the measles, mumps, and rubella ["MMR"] vaccine was causal, that the vaccines containing thimerosal, a mercury-based preservative, were causal, or that a combination of the MMR vaccine and vaccines containing thimerosal were causal.

[4] National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3755. Hereinafter, for ease of citation, all "§" references to the Vaccine Act will be to the pertinent subparagraph of 42 U.S.C. § 300aa (2006).

[5] The OAP is discussed in detail in *Snyder v. Sec'y, HHS*, No. 01-162V, 2009 WL 332044, at *4 (Fed. Cl. Spec. Mstr. Feb. 12, 2009), *aff'd*, 88 Fed. Cl. 706 (2009) and *Dwyer v. Sec'y, HHS*, 2010 WL 892250, at *3 (Fed. Cl. Spec. Mstr. Mar. 12, 2010).

[6] 42 C.F.R. § 100.3 (2011).

[7] Section 11(c)(2) of the Vaccine Act and Vaccine Rule 2 require that petitions be accompanied by medical records and affidavits.

[8] The five sets of medical records were initially filed as Petitioners' Exhibits ["Pet. Ex."] 13.1-13.10; 14.1-14.3; 15.1; 16.1-16.2; and 17.1. Petitioners had incorrectly correlated the exhibit numbers with the docket entry number (e.g., the exhibit filed in docket entry 15 was labeled as Exhibit 15.1). Petitioners re-

further activity occurred in this case until after the conclusion of the appeals in the OAP test cases. On January 25, 2011, in light of the test case findings, petitioners were ordered to inform the court if they wished to proceed with their claim or exit the Vaccine Program. In the event, they decided to proceed, petitioners were ordered to file an amended petition. Order, issued Jan. 25, 2011. Petitioners filed an amended petition on June 29, 2011, alleging that one or more of the vaccinations that Sahra received between birth and four and half years of age "caused or exacerbated progressive encephalopathy with autistic features" and the sequelae. Amended Petition ["Am. Pet."] at 2.

This case was reassigned to me on July 1, 2011. During a status conference on July 20, 2011, I advised petitioners' counsel that this claim appeared to have been filed outside the Vaccine Act's 36 month statute of limitations.[9] Order, issued July 20, 2011.

Between October 2011 and April 2012, petitioners filed additional exhibits detailing Sahra's health from birth to early childhood. On February 27, 2012, respondent was ordered to file a statement indicating whether, based on the available medical records, she believed petitioners' claim should proceed.

On April 11, 2012, in lieu of filing a statement, respondent moved to dismiss petitioners' claim, asserting that the petition was filed after the expiration of the Vaccine Act's statute of limitations. Motion at 1, 4-5. Respondent argued that the petition should have been filed no later than November 2, 2007, because the first symptom or manifestation of onset of Sahra's autism spectrum disorder ["ASD"][10] occurred as early as November 2, 2004. *Id*. at 2-3, 5.

On July 16, 2012, petitioners filed a joint opposition to respondent's motions to dismiss in both of their children's cases.[11] In their response, petitioners assert that the diphtheria, tetanus, acellular, and pertussis ["DTaP"] and inactivated polio virus ["IPV"] administered on January 8, 2007, significantly aggravated Sahra's pre-existing

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filed these records as Pet. Exs. 1-7 on August 3, 2011.

[9] At the time of this status conference, interpretation of the Vaccine Act's statute of limitations was under review by the U.S. Court of Appeals for the Federal Circuit. The Federal Circuit, siting *en banc*, heard oral argument in *Cloer v. Sec'y, HHS,* on May 10, 2011. Because the outcome of that case could affect my determination of timeliness in this case, I opted to wait for the Federal Circuit's decision before ordering petitioners to obtain an expert report. On August 5, 2011, the Federal Circuit reiterated that the first symptom recognized by the medical community at large as a symptom of a disorder triggered the running of the statute of limitations in Vaccine Act cases. *Cloer v. Sec'y, HHS*, 654 F.3d 1322, at *1335 (Fed. Cir. 2011), *cert. denied*, 132 S. Ct. 1908 (2012).

[10] "Autism spectrum disorder" is an umbrella term encompassing several neurological disorders manifesting in early childhood with impairments in communication and social interaction, and the display of restricted, repetitive, or stereotypical patterns of behavior, interests, and activities. A more complete description of the disorder is contained in *White v. Sec'y, HHS*, No. 04-337V, 2011 WL 6176064 (Fed. Cl. Spec. Mstr. Nov. 22, 2011).

[11] Petitioners also filed a petition on behalf of their daughter Osob. (No. 08-308V).

mitochondrial disorder and that the short-form petition filed on April 22, 2008, was therefore filed well within the statute of limitations period. Response at 2, 5.

On July 17, 2012, petitioners filed Mr. Hashi's affidavit, in which he provides his recollection of what happened to Sahra after she received the alleged causal vaccines. Pet. Ex. 18.

II. Relevant Medical History.

A. Birth to Fourth Birthday (November 2002 to November 2006).

1. Early Health and Development.

Sahra was born on November 2, 2002. Pet. Ex. 1, p. 1. She was delivered full-term without any complications and her Apgar scores were 9 and 9,[12] reflective of a healthy newborn. *Id.*, pp. 1-2. She received a hepatitis B vaccine prior to her discharge from the hospital, *id.*, p. 4, and continued to receive routinely-administered childhood vaccinations in her first three years.[13] Pediatrician Lawrence Stratton's records indicate that Sahra continued to meet the appropriate developmental milestones at two and four months of age. Pet. Ex. 4-2,[14] pp. 48-50, 53-55.

2. Initial Concerns of Developmental Delay.

Doctor Stratton first expressed concern about Sahra's development at her six month well child visit on May 15, 2003. Pet. Ex. 4-2, pp. 43, 46. At that visit, he noted "[d]evelopmental delay and referred Sahra for an Early Intervention evaluation. *Id.*, p. 46. Later, at Sahra's nine month well child visit on August 13, 2003, Dr. Stratton noted "mild motor delays." *Id.*, p. 41.

On April 2, 2004, Sahra was seen by Dr. Stratton to follow up on his concerns regarding her development. Pet. Ex. 4-2, p. 29. Doctor Stratton noted that Sahra was

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[12] An Apgar score is a numerical assessment of a newborn's condition (with lower numbers indicating problems), usually taken at one minute and five minutes after birth. The score is derived from the infant's heart rate, respiration, muscle ton, reflex irritability, and color, with from zero to two points awarded in each of the five categories. DORLAND'S ILLUSTRATED MEDICAL DICTIONARY ["DORLAND'S"] at 1682 (32nd ed. 2012).

[13] Between November 2002, and May 2004, Sahra received the follow vaccines: hepatitis B vaccine on November 3, 2002, and again on December 11, 2002; DTaP, Haemophilus influenzae type B ["Hib"], IPV, and pneumococcal conjugate vaccines ["Prevnar"] on January 9, 2003, March 13, 2003, and on May 15, 2003; IPV, measles, MMR, and varicella vaccines on November 4, 2003; and DTaP, Hib and Prevnar on May 20, 2004. *See* Pet. Ex. 19.

[14] Petitioners' Exhibit 4 was filed as two separate pdf files; the first (4-1) containing 64 pages and the second (4-2) 87 pages. Instead of consecutively numbering the pages from the two files 1 to 151, petitioners individually numbered the contents of the files. Therefore, this decision refers to Exhibits 4-1 and 4-2 and not simply Exhibit 4.

making slow progress, with no loss of milestones, and recommended continuing the Early Intervention services. *Id.*, p. 32. At Sahra's belated 15 month well child visit on May 20, 2004, when she was more than 18 months of age, she was still not walking and had a vocabulary of six to twelve words. *Id.*, p. 18.

On September 7, 2004, when she was about 22 months of age, Sahra was diagnosed with developmental delay by her pediatrician.[15] Pet. Ex. 4-1, pp. 31, 33. At that time, Dr. Stratton noted that Sahra had not lost any milestones, could speak approximately 20 words, understands well, but had not begun walking and was "following [the] same pattern as [her] sister." *Id.*, p. 31, 33.

3. Diagnosis of Autism.

In October 2006, Dr. Peter Masucci, Sahra's pediatrician at the time, noted that she had been diagnosed with autistic disorder. Pet. Ex. 11, pp. 17-18. The source for his notation was not specifically identified, but likely was based on two evaluations Sahra underwent in September 2006.

On September 26, 2006, at almost four years of age, Sahra was evaluated at the Massachusetts General Hospital's ["MGH"] Department of Speech, Language, and Swallowing Disorders by Dr. Jean Ashland. Based on the report, Sahra had normal speech and language development in her early childhood and began regressing at approximately two years of age. Pet. Ex. 11, pp. 91. According to petitioners, Sahra used two to three word combinations at two years of age and was no longer using more than single words. *Id.* Although the evaluation was focused on her expressive and receptive language skills, the report did note that Sahra exhibited decreased eye contact, lack of imaginative play, and general "deficits in social/pragmatic and play skills." *Id.*, pp. 92-93. Doctor Ashland was concerned about her speech and language regression, particularly in light of the family history of autism.[16] *Id.*, p. 92.

Earlier in the month, on September 19, 2006, petitioners met with the Everett Public Schools concerning Sahra's Individualized Education Program ["IEP"]. The IEP form noted her disability as pervasive developmental delay, and indicated that she "was on the spectrum of an individual with Autism." Pet. Ex. 15, pp. 2-3. Pervasive developmental disorder or "PDD" is the umbrella term used in the fourth edition of the Diagnostic and Statistical Manual of Mental Disorders ["DSM"] for certain developmental disorders, including autism (also referred to as autistic disorder), pervasive developmental disorder-not otherwise specified ["PDD-NOS"], and Asperger's

[15] In earlier records developmental delay was listed in the "Problems" section of the visit note. The record from September 7, 2004 is the first to include developmental delay in the "Diagnosis" section of the note. Within the diagnosis section of the record from the September 7, however, the "recorded start date" for her developmental delay is May 15, 2003, the date of Sahra's six month well child visit.

[16] Sahra's older sister, Osob, has a diagnosis on the autism spectrum. Additionally, Sahra's cousin has a diagnosis of autism. Pet. Exs. 4-2, p. 32; 7, p. 17.

Disorder.[17] There is possible confusion between "PDD" (the umbrella term referring to the general diagnostic category) and "PDD-NOS," which is a specific diagnosis within the general diagnostic category of PDD. It is not uncommon for parents and even health care providers to use these terms in non-specific ways, such as referring to a child as having an "autism diagnosis," even though the specific diagnosis is PDD-NOS. In conveying that Sahra had pervasive developmental delay and was on the autism spectrum, the school official was likely referring to the DSM-IV umbrella category of PDD when describing the nature of her disability and reason for the IEP evaluation.

B. Ages Four and Five (November 2006 to November 2008).

1. Primary Care Visits.

On January 8, 2007, at her four year well child visit, Dr. Masucci noted that Sahra had unspecified pervasive developmental disorder with "up and down" progression. Pet. Ex. 11, pp. 9-10. She received the DTaP and IPV vaccines at this visit.

She did not present to the pediatrician again until March 23, 2007, about three months after receiving the January 2007 vaccines. Pet. Ex. 11, pp. 7-9. She was diagnosed with acute sinusitis. *Id.*, p. 8. No concerns about a vaccine reaction were expressed at this visit. She was seen on April 2, 2007, and diagnosed with possible viral gastroenteritis or an upset stomach caused by the antibiotics she was prescribed for her sinusitis. *Id.*, p. 7. Again, no concerns of a vaccine-related injury were recorded.

On May 17, 2007, Sahra was seen with complaints of a runny nose and cough. Pet. Ex. 11, pp. 3-5. Her problem history was reviewed and remained the same as September 9, 2006. She was diagnosed with acute bronchitis. *Id.*, p. 5. Less than a month later, on June 9, 2007, Sahra returned to Dr. Masucci, where she was "more interactive and cooperative than usual" during her examination, and was diagnosed with an acute upper respiratory infection. *Id.*, pp. 2-3.

Her five year well child visit was performed by Dr. Marc Rosenthal with Harvard Vanguard Medical Associates, Burlington Pediatrics on November 19, 2007. Pet. Ex. 10, p. 8. It was Sahra's first visit to the practice group, and prior to the visit Dr. Rosenthal had reviewed her medical records and spoken with her neurologist. *Id.*, p. 9. He questioned whether Sahra had experienced a true regression of skills, indicating that she probably exhibited "slow increase and variability of development" and "continues to gain new skills but others seem to fall away." *Id.*, p. 10. Sahra returned to Burlington Pediatrics on January 15, 2008. Doctor Hoder diagnosed her with a probable upper respiratory infection. *Id.*, p. 7.

[17] The fifth edition of the DSM, released in May 2013, uses the umbrella term "Autism Spectrum Disorder" rather than PDD.

2. Visits to Medical Specialists.

Doctor Ann Neumeyer, a pediatric neurologist affiliated with MGH's Learning and Developmental Disabilities Evaluation and Rehabilitation Services ["LADDERS"], examined Sahra on November 15, 2006. Based on parental reports, Dr. Neumeyer indicated that "after the age of 2 [Sahra] began loosing [*sic*] some words." Pet. Ex. 7, p. 24. Doctor Neumeyer noted the strong history of developmental regression in Sahra's family, and suggested that Sahra was having a similar developmental regression. *Id.*, p. 26. Sahra returned to LADDERS in December 2006. Doctor Neumeyer was concerned that there was a genetic component to the developmental issues present in Sahra and her older sister and encouraged a thorough consideration of possible etiologies. *Id.*, pp. 21-22.

Sahra was evaluated Children's Hospital of Boston's Developmental Medicine Center on January 23, 2007, by Dr. Ronald Becker, a behavioral and developmental pediatrician, and Dr. Rachel Hundley, a staff psychologist. Pet. Exs. 3, pp. 2-13; 11, pp. 71-78. They noted that when Sahra was between 36 and 40 months of age she may have experienced language regression, and that she currently spoke only single words or made non-word vocalizations. Pet. Ex. 3, p. 3. Based on the evaluation, which used various assessment procedures,[18] Sahra met the diagnostic criteria for autistic disorder. She was also diagnosed with mental retardation, severity unspecified. Pet. Ex. 3, p. 10.

On July 12, 2007, Dr. Neumeyer reported that Sahra appeared to have made significant progress since her last visit to LADDERS on March 27, 2007. Pet. Ex. 11, p. 61. She was using single words and occasionally used full and scripted sentences. *Id.* Doctor Neumeyer also noted that what was previously described as a large regression was in fact more behavioral and Sahra "has not really lost much language at all since birth." *Id.*

Sahra and her older sister, Osob, had an appointment at MGH's Mitochondrial Clinic on August 15, 2007. They were evaluated by pediatric neurology resident Dr. David Dredge and Dr. Katherine Sims, the attending physician. Her parents reported that their concerns started when she was approximately two years of age, and that they felt she had a significant decline in language skills around 24 to 30 months of age. Pet. Ex. 11, p. 53. Given her abnormal laboratory results in the past, Drs. Dredge and Sims suggested that Sahra may have an "underlying disorder of cellular metabolism contributing to her [austistic] symptoms." *Id.*, p. 54. Because of the similarity in symptoms between Sahra and Osob, petitioners elected to initially only perform genetic tests on Osob. Depending on the results, testing would then be conducted on Sahra. *Id.*, p. 55.

The July 3, 2008 consult note from LADDERS indicates that although Sahra had

[18] The procedures included the Stanford-Binet Intelligence Scales, Bayley Scales of Infant and Toddler Development-Third Edition, Autism Diagnostic Observation Schedule, and the Vineland Adaptive Behavior Scales. Pet. Ex. 11, pp. 72-73.

not undergone a muscle biopsy, based on the results from Osob's biopsy showing a complex I electron transplant chain deficiency, she had begun to take a mitochondrial cocktail.[19] Pet. Ex. 7, p. 10. Since starting the cocktail in April 2006, Sahra had made progress in her language and communication skills. However, because this improvement coincided with an improvement in the school program she was attending, Dr. Neumeyer noted the cause for her progress could not be conclusively identified but recommended that Sahra continue taking the mitochondrial cocktail. *Id.*, p. 11.

D. Further Exploration of Possible Mitochondrial Disorder.

On January 22, 2010, Sahra was examined by Dr. Daniel Doody. She was referred to him for a consideration of skin and muscle biopsies. He reported that Sahra began to exhibit signs of a developmental regression at age 4. Pet. Ex. 9, p. 21-22. However, a week later during the pre-anesthesia telephone consult, it was reported that her language regression began at age 3. *Id.*, p. 23.

Sahra underwent a muscle and skin biopsy on February 3, 2010. Pet. Ex. 9, pp. 151, 178-185. The electron microscopy analysis of the muscle tissue revealed "small subsarcolemnal clusters of mitochondria with pleomorphic shapes and increased internal complexity." *Id.*, p. 186. Pathologist Dr. Anat Stemmer-Rachamimov indicated that those findings are "non-specific, but may be seen in mitochondrial disorders." The skin biopsy uncovered "no definitive evidence of mitochondrial abnormality." *Id.*, p. 187.

The Baylor College of Medicine's Medical Genetics Laboratory reported the results of their mtDNA complex 1 subunits sequencing analysis of Sahra's sample on May 24, 2010. The analysis detected "an apparently homoplasmic familial m.5194C>T (p.P242L, ND2) variant." Pet. Ex. 3, p. 17. The report noted that the laboratory was requested to evaluate the sample for the found variant, which had previously been found in Sahara's mother and older sister. Other regions of the mitochondrial genome were not sequenced. *Id.* The ND2 gene variant observed was listed in MitoMap as a polymorphism, but at the time of the report was not listed in mtDB.[20]

Sahara had a follow-up visit at MGH's Mitochondrial Clinic on October 6, 2010. Doctor Sims reported that since her April 2010 clinic visit, Sahra had been making progress at school. Ms. Weged expressed frustration as to the pace of the progress, but agreed there had been no regression in skills. Pet. Ex. 9, p. 129. In reviewing the biopsy results, Dr. Sims noted that the observed "mtDNA change is of unclear significance." *Id.*, p. 130.

On June 2, 2011, Sahra had a follow-up appointment with Dr. Neumeyer at

[19] The cocktail consisted of thiamine, riboflavin, vitamin C, vitamin E, carnitine, alpha-lipoic acid, coenzyme Q, and creatine monohydrate. Pet. Ex. 7, p. 11.

[20] Petitioners' Exhibit 3, p. 17 referencing http://www.mitomap.org and http://www.genpat.uu.se/mtDB.

LADDERS.[21] The past medical history section of the consult note indicates that Sahra's evaluation at the Cleveland Clinic did not confirm or uncover a mitochondrial disorder. Pet. Ex. 9, p. 113. No date was given for the evaluation.

III. Applying the Facts to the Law.

A. Untimely Filing.

The Vaccine Act's statute of limitations provides in pertinent part that, in the case of:

> a vaccine set forth in the Vaccine Injury Table which is administered after October 1, 1988, if a vaccine-related injury occurred as a result of the administration of such vaccine, no petition may be filed for compensation under the Program for such injury after the expiration of 36 months after the date of the occurrence of the first symptom or manifestation of onset or of the significant aggravation of such injury . . .

§ 300aa-16(a)(2).

Because petitioners filed the petition on behalf of Sahra on April 22, 2008, the first symptom or manifestation of onset of Sahra's autism cannot have occurred before April 22, 2005, in order for the petition to be considered timely. See *Markovich v. Sec'y, HHS*, 477 F.3d 1353, 1357 (Fed. Cir. 2007) (holding that "either a 'symptom' or a 'manifestation of onset' can trigger the running of the statute [of limitations], whichever is first"); *Cloer v. Sec'y, HHS*, 654 F.3d 1322, 1335 (Fed. Cir. 2011) (holding that the "analysis and conclusion in *Markovich* is correct. The statute of limitations in the Vaccine Act begins to run on the date of the occurrence of the first symptom or manifestation of onset."). Furthermore, the date of the occurrence of the first symptom or manifestation of onset "does not depend on whether petitioner knew or reasonably should have known" about the injury. *Cloer*, 654 F.3d at 1339. Nor does it depend on petitioner's knowledge as to the cause of injury. *Id*. at 1338.

In *Cloer*, the Federal Circuit also acknowledged that equitable tolling applies to Vaccine Act cases, but only under very limited circumstances, such as when a petitioner was the victim of fraud or duress, or when a procedurally deficient pleading was timely filed. *Cloer*, 654 F.3d at 1344-45. The Federal Circuit rejected the notion that equitable tolling should apply only because the application of the statute of limitations would otherwise deprive a petitioner from bringing a claim. *Id*.

The medical records establish, and petitioners appear to concede, that the claim was not timely filed. Doctor Stratton's records clearly convey that concerns regarding Sahra's developmental delay existed as early as May 15, 2003, when he referred her

[21] This is the most recent relevant medical record filed. The most recent record filed is from July 11, 2011 when Sahra was seen for a swollen bug bite on her check. There was no evidence of infection, and petitioners were instructed to observe the area. Pet. Ex. 9, p. 60.

for Early Intervention services. While previous records listed developmental delay as a "problem," on September 7, 2004, Dr. Stratton listed it as a "diagnosis." At the same visit, he noted that she only spoke 20 words.[22] Additionally, a number of medical records note that parental concerns regarding Sahra's speech began around November 2004, when she was two years of age. I thus find that the first symptom or manifestation of Sahra's autism spectrum disorder occurred prior to the critical date of April 22, 2005.

Petitioners have not asserted any extraordinary circumstances which would merit equitable tolling of the Vaccine Act's statute of limitations. I therefore conclude that this case was untimely filed.

B. Significant Aggravation.

To recover under a significant aggravation theory, petitioners must demonstrate that the vaccination caused a "change for the worse in a preexisting condition which results in markedly greater disability, pain, or illness accompanied by substantial deterioration in health." § 33(4); *Hennessey v. Sec'y, HHS*, No. 01-190V, 2009 WL 1709053 at *1 (Fed. Cl. Spec. Mstr. May 29, 2009), *aff'd*, 91 Fed. Cl. 126 (2010). In *Loving v. Sec'y, HHS*, 86 Fed. Cl. 135, 144 (2009), the Court of Federal Claims created a six-factor test for significant aggravation, requiring a petitioner to establish by preponderant evidence: (1) the vaccinee's condition prior to administration of the vaccine; (2) the vaccinee's current condition or condition following the vaccine; (3) whether the comparison of the two conditions constitutes a significant aggravation of the person's condition; (4) a medical theory causally connecting a significantly worsened condition to the vaccine; (5) a logical sequence of cause and effect demonstrating that the vaccine was the reason for the significant aggravation; and (6) a proximate temporal relationship between the vaccine and the significant aggravation. This test has been cited with approval by the Federal Circuit. *W.C. v. Sec'y, HHS*, 704 F.3d 1352, 1357 (Fed. Cir. 2013).

Less than a month after her January 8, 2007 vaccinations, those petitioners point to in their response to respondent's motion as significantly aggravating her condition, Sahra underwent a developmental evaluation at Children's Hospital of Boston. The report from her evaluation does not mention any parental concerns about a recent regression or change in Sahra's development. Doctors Becker and Hundley instead reported that that parental concern of a regression in language skills occurred between November 2005 and May 2006, when she was 36 to 40 months of age.[23] In July 2007,

[22] The vocabulary of a typical child substantially grows between 18 and 24 months of age, increasing from around 10-15 words to 50-100 words. R. Kliegman, et al., NELSON TEXTBOOK OF PEDIATRICS (19th ed. 2011) at 27. At the time of this visit, Sahra was 22 months of age.

[23] In most of Sahra's developmental evaluations, petitioners reported their concerns arose when she was 24 to 30 months of age. *See, e.g.*, Pet. Exs. 11, pp. 53-54 (August 15, 2007 MGH Mitochondrial Clinic evaluation) and 91-92 (September 26, 2006 MGH Department of Speech, Language and Swallowing Disorders evaluation); 7, pp. 24-25 (November 15, 2006 MGH LADDERS consultation).

Dr. Neumeyer reported significant progress in Sahra's language skills. Additionally, she noted that what had previously been categorized as a regression in Sahra's skills was more likely behavioral in nature and stated that Sahra had not undergone a significant loss of language. Thus, it appears that the factual support for a significant aggravation claim is lacking.[24]

III. Conclusion.

The Vaccine Act provides that "no petition may be filed . . . after the expiration of 36 months after the date of the occurrence of the first symptom or manifestation of onset . . . of such injury." § 16(a)(2). There is preponderant evidence that the causation in fact claim was not filed within the 36-month period and petitioners have failed to demonstrate any extraordinary circumstances warranting equitable tolling. **Therefore, petitioners' causation in fact claim is dismissed.**

The contemporaneous record fails to demonstrate any proximate temporal relationship sufficient to support a colorable significant aggravation claim, suggesting petitioners lack a reasonable basis to proceed on a significant aggravation theory. Nevertheless, if petitioners intend to pursue such a claim, as is suggested by their response to respondent's motion to dismiss, they must file a second amended petition by no later than **Wednesday, September 25, 2013**. Additionally, petitioners must file an expert report supporting a significant aggravation claim by **Monday, November 25, 2013**. **A failure to meet these deadlines will result in dismissal of this petition.**

IT IS SO ORDERED.

s/Denise K. Vowell
Denise K. Vowell
Special Master

[24] On July 17, 2012, petitioners filed an affidavit from Mr. Hashi. He indicated that after her January 8, 2007 vaccinations, Sahra cried inconsolably, had a high fever, seemed spaced out, exhibited decreased response to her environment, would not communicate, and became monotonic with her speech. Pet. Aff. at 3. The symptoms listed in his affidavit do not match those contained in the contemporaneous medical records. Conflicts between contemporaneous medical records and subsequent statements are common in Vaccine Act cases, with Special masters frequently according more weight to the contemporaneously recorded medical symptoms than those recounted in later medical histories, affidavits, or trial testimony. "It has generally been held that oral testimony which is in conflict with contemporaneous documents is entitled to little evidentiary weight." *Murphy,* 23 Cl. Ct. at 733 (1991). *See also Cucuras v. Sec'y, HHS*, 993 F.2d 1525, 1528 (Fed. Cir. 1993). Memories are generally better the closer in time to the occurrence reported and when the motivation for accurate explication of symptoms is more immediate. *Reusser v. Sec'y, HHS*, 28 Fed. Cl. 516, 523 (1993). Inconsistencies between testimony and contemporaneous records may be overcome by "clear, cogent, and consistent testimony" explaining the discrepancies. *Stevens v. Sec'y, HHS*, No. 90-221V, 1990 WL 608693, at *3 (Fed. Cl. Spec. Mstr., Dec. 21, 1990).